

DATA TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

Stockton (Israel) Ltd.
c/o Wagner Regulatory Associates
PO Box 640, 7217 Lancaster Pike, Suite A
Hockessin, DE 19707

2. Regulatory Action In Support Of Which This Package Is Submitted

Application for Registration
STK-73; ABN: Timorex Act®

3. Transmittal Date

August 17, 2018

4. List of Submitted Studies

50639301	STK-73; ABN: Timorex Act® Product Identity and Composition, Description of Materials, Description of Formulation Process, Preliminary Analysis, Discussion of Impurities and Certified Limits, OPPTS 830.1550, 830.1600, 830.1650, 830.1670, 830.1700, 830.1750
50639302	STK-73 (Tea Tree Oil 12.5%): Method Validation and Demonstration of Homogeneity and Stability of Test Item in Dose Formulations, Study No. G12114, OPPTS 830.1800
50639303	Determination of Colour, Odour, and Physical State of STK-73 (Tea Tree Oil 12.5%), Study No. G11924, OPPTS 830.6302, 830.6303, 830.6304
50639304	Accelerated Storage Stability Test by Heating at Elevated Temperature of 54±2°C of STK-73 (Tea Tree Oil 12.5%), Study No. G11928, OPPTS 830.6313
50639305	Oxidation/Reduction: Chemical Incompatibility of STK-73 (Tea Tree Oil 12.5%), Study No. G11925, OPPTS 830.6314
50639306	Determination of Flash Point of STK-73 (Tea Tree Oil 12.5%), Study No. G11926, EEC A.9
50639307	Determination of Explosive Properties of STK-73 (Tea Tree Oil 12.5%), Study No. G11927, EEC A.14
50639308	Miscibility of STK73 (Tea Tree Oil 12.5%), Study No. G11931, OPPTS 830.6319
50639309	Corrosion Characteristics of STK-73 (Tea Tree Oil 12.5%), Study No. G11932, ASTM G-31-72-Principally
50639310	Determination of pH of 1% Aqueous Suspension and Acidity/Alkalinity of STK-73 (Tea Tree Oil 12.5%), Study No. G11933, OPPTS 830.7000
50639311	Determination of Viscosity of STK-73 (Tea Tree Oil 12.5%), Study No. G11935, OPPTS 830.7100
50639312	Determination of Density of STK-73 (Tea Tree Oil 12.5%), Study No. G11936, OPPTS 830.7300
50639313	STK-73 (Tea Tree Oil 12.5%): Acute Oral Toxicity Study (Up-and-Down Procedure) in Wistar Rats, Study No. G11941, OPPTS 870.1100
50639314	STK-73 (Tea Tree Oil 12.5%): Acute Dermal Toxicity Study in Wistar Rats, Study No. G11942, OPPTS 870.1200
50639315	STK73 (Tea Tree Oil 12.5%): Acute Inhalation Toxicity Study in Wistar Rats, Study No. G11943, OPPTS 870.1300
50639316	STK-73 (Tea Tree Oil 12.5%): Acute Eye Irritation/Corrosion Study in New Zealand White Rabbits, Study No. G11945, OPPTS 870.2400
50639317	STK-73 (Tea Tree Oil 12.5%): Acute Dermal Irritation/Corrosion Study in New Zealand White Rabbits, Study No. G11944, OPPTS 870.2500
50639318	STK-73 (Tea Tree Oil 12.5%): Skin Sensitization Study (Magnusson and Kligman Test) in Guinea Pigs, Study No. G11946, OPPTS 870.2600
50639319	Timorex Act® (Tea Tree Oil 12.5%) Product Chemistry – Group B Request for Waiver for Certain Physical/Chemical Properties, OPPTS 830.6321; 830.7050; 830.7200; 830.7220; 830.7370; 830.7520; 830.7550; 830.7560; 830.7570; 830.7840; 830.7860; 830.7950
50639320	STK-73 (Tea tree oil 12.5%) Acute Effects on the Honeybee <i>Apis mellifera</i> (Hymenoptera, Apidae), Study No 160927ST/IBA17370, OECD 213,214
50639321	STK-73 (Tea tree oil 12.5%): Avian acute oral toxicity study in Japanese quails, Study No. G12113, OPPTS 850.2100
50639322	STK-73 (Tea tree oil 12.5%) Acute Immobilization Test to <i>Daphnia magna</i> , Semi-static, 48 hours, in a Closed System without Headspace, Study No. 160927ST/DAI17370, OECD 202
50639323	STK-73 (Tea tree oil 12.5%) Fish (Rainbow trout), Acute Toxicity Test, Semi-Static, 96 hours, Study No. 160927ST/FAR17370, OECD 203
50639324	Timorex Act®/STK-73 (Tea Tree Oil 12.5%) Request for Waiver for Certain Nontarget Organisms Toxicity Data, OPPTS 850.2200, 850.4100, 850.4150

50639325 Timorex Act®/STK-73 (Tea Tree Oil 12.5%) Request for Reduced Restricted Entry Interval

Company Official:

Rachel L Hardie
Authorized Agent



Signature

Company Name: Stockton (Israel) Ltd.

Company Contact:

Rachel L Hardie
Authorized Agent

302-365-7289
Phone